K080933

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Appendix II 510(K) Summary

Non-Confidential Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance the requirements of 21 CFR 807.92

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Official Contact: **Lei Chen Manager**

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Proprietary or Trade Name: **MD100 Handheld ECG Monitor**

Common/Usual Name: **Handheld, ECG Monitor**

Classification: **Class II**

Device: **MD100 Handheld ECG Monitor**

Predicate Devices: **Omron HCG-801 Portable ECG Monitor K060766**

Device Description:

The applicant device of Handheld ECG Monitor MD100 is a handheld device, which can records cardiac event data and displays the data in a clear and precise waveform.

The ECG Monitor is made up of signal input unit, signal amplify unit, CPU, Display unit, power unit and storage chip. They are all in one PCB that is designed and made by our company.

The MD100 Handheld ECG Monitor is activated by the user whenever symptoms are experienced. The recorded data serves as reliable evidence and are later shown to physicians or other health care professionals for confirmation of these symptoms. When a user feels that a cardiac event is occurring, the utilization of MD100 has the feature of recording this real time data that is normally difficult to capture.

The applicant device has "data upload" function which controlled by hardware, it can transmit the data measured by the device to computer via the USB port. The software attached with the device named " Keep-it-easy" in CD ROM, which is use for store and playback the data collected by MD100 ECG monitor. The "Keep-it-easy" software needs to install in the computer by user. The "Keep-it-Easy" software CD ROM is the accessory of the applicant device.

The applicant device has low battery voltage indication function. The power of the monitor works supplied by 2*AAA batteries.

Indications for Use:

The Handheld ECG Monitor MD100 is intended for use in non-invasive recording and displaying ECG waveform by adult patients. In addition, it also can provide to the treating physician with relevant data on the cardiac rhythm in hospital patients. It is immediately available at any time to manually record transient cardiac events, suitable for patient and professional use, helpful in determining the cardiac rhythm at the time of symptoms. This ECG monitor allows the patient to record their ECG data into the device memory for display by healthcare professional during office visits.

The product is not a conventional diagnostic tool.

Non-Confidential Summary of Safety and Effectiveness

Environment of Use – Prescription

Device Attributes:

Features	MD100
Environment of use	Prescription use for self testing anywhere and anytime.
Patient Population	Adult
Type of waveform	Real time ECG Waveform display.
Heart Rate Range	30-240 beats/min
Software driven	Yes
Materials in patient contact	ABS, Metal
Standard met	IEC 60601-1, IEC 60601-1-2, AAMI EC38
Measurement Rate	30 Seconds
Components	2 AAA Batteries, Hanging rope, Dustproof cover, Operation manual, USB Cable(Optional)
Operating conditions	5℃~40 ℃
Storage conditions	-20℃～40℃
	≤RH80%
Dimensions(mm)	136mm(W)×84mm(H)×21mm(D)
Weight(kg) without battery	100 g

Non-Confidential Summary of Safety and Effectiveness

Differences Between Other Legally Marketed Predicate Devices

The MD100 Handheld ECG Monitor is viewed as substantially equivalent to predicate device: Omron HCG-801 portable ECG Monitor. (K060766)

The Omron HCG-801 portable ECG Monitor features real-time display of waveform and ECG recording.

BASIC COMPARISONS BETWEEN MD100 and HCG-801.

	MD100	HCG-801
SUBSTANTIAL EQUIVALENCE COMPARISONS		**K060766**
Intended Use	**Same**	**Same**
Prescription/Over the Counter	**Prescription**	**Prescription**
Display of waveform	**Display real-time ECG waveform**	**Display real-time ECG waveform**
Type of Transmission	**USB Transmission**	**Non-USB Transmission**
Transmission Tool	USB	Standard compact memory card
Lead placement on body	**Palm and Chest Placement**	**Chest Placement**
Multiple Event Recording	**Yes**	**Yes**
Base-line stabilization	**Yes**	**Yes**
Battery Life Indicator	**Yes**	**Yes**
Lead Cable	**No**	**No**
Pacemaker Detection	**No**	**No**

Non-Confidential Summary of Safety and Effectiveness

In summary, the MD100 Handheld ECG Monitor is substantially equivalent to Omron HCG-801 portable ECG Monitor in the following ways:

MD100 Handheld ECG Monitor is schematically similar to Omron HCG-801 portable ECG Monitor.

Both devices are handheld, portable, personal type ECG monitor. MD100 Handheld ECG Monitor does provide the data transmission option which is not an option the Omron HCG-801 ECG offers. Both devices are prescription devices intended for self-testing by patients under doctors' supervision. In both devices, user can place device on his/her chest and hold it steadily to test although the MD100 Handheld ECG Monitor provides another method that test by the centre of the palm. In both devices the user is not required to apply external electrodes to the body. Both devices have the capability to record real time heart rhythm waveform and heart beat and store data that can be displayed and downloaded.

The MD100 Handheld ECG Monitor constitutes a safe, accurate, and reliable means for recording of ECG data. When this device is used as intended it is as safe and effective as the predicate device. As shown, MD100 device has generally the same technological characteristics and intended use as Omron HCG-801 portable ECG Monitor but more advantageous and practical in terms of ease of use and reliability.

Validation testing contained in the submission demonstrates that any differences in their technological characteristics do not raise any new questions of safety and effectiveness. When the device is used as it is intended it poses no adverse health effects of safety risks to users.

Performance Testing:

We performed the following bench testing to demonstrate safety and effectiveness and equivalency to the predicate device:

IEC 60601-1 Medical Electrical Equipment Part 1: General Requirements for Safety; Amendment 1, 1991-11,Amendment 2,1995-03. Version 1995
EMC tests according to IEC 60601-1-2 Medical Electrical Equipment Part 1-2: General Requirements for Safety-Collateral Standard: Electromagnetic Compatibility Requirements and Tests. Version 2001
AAMI EC38 Ambulatory Electrocardiographs
ISO 10993, Biological Evaluation of Medical Devices

Non-Confidential Summary of Safety and Effectiveness

Conclusion

Based upon the performance testing and comparison to legally marketed predicate device (for indications for use, technology, and performance) we have demonstrated that the MD100 Handheld ECG Monitor is substantially equivalent in safety and effectiveness to the predicate device.

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 6 2008

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Shanghai 200030, CHINA

Re: K080933
Trade/Device Name: Handheld ECG Monitor MD 100
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (Two)
Product Code: DPS
Dated: September 18, 2008
Received: September 19, 2008

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix I Indications for Use Form

510(k) Number: K080993

Device Name: Handheld ECG Monitor MD100

Indications for Use:

The Handheld ECG Monitor MD100 is intended for use in non-invasive recording and displaying ECG waveform by adult patients. In addition, it also can provide to the treating physician with relevant data on the cardiac rhythm in hospital patients. It is immediately available at any time to manually record transient cardiac events, suitable for patient and professional use, helpful in determining the cardiac rhythm at the time of symptoms. This ECG monitor allows the patient to record their ECG data into the device memory for display by healthcare professional during office visits.

The product is not a conventional diagnostic tool.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Donna R Vachney

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K080933